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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,056	MARUYAMA ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on th cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *1,2,4 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3, 5, 6, 7* is/are rejected.

7)☒ Claim(s) *3, 5* is/are objected to.

8)☒ Claim(s) *1-8* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7-2002* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. The restriction requirement mailed 9/9/03 is WITHDRAWN in view of the restriction requirement set forth herein, in accordance with conversations held between Examiner Switzer and Vincent Shier on 9/5/03 (when a provisional election was made) and 9/8/03 (confirming that a written requirement for restriction had accidentally been mailed by a different examiner after the telephonic election was already made; see interview summary mailed 9/22/03).

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to oligonucleotides for the detection of VT1 RNA, classified in class 536, subclass 24.3.

II. Claim 2, drawn to oligonucleotides for the detection of VT2 RNA, classified in class 536, subclass 24.3.

III. Claims 3, 5, 6, and 7, drawn to methods for the detection of VT1 RNA, classified in class 435, subclass 91.2.

IV. Claims 4, 5, 6, and 8, drawn to methods for the detection of VT2 RNA, classified in class 435, subclass 91.2.

The inventions are distinct, each from the other because of the following reasons:

3. The products of groups I and II are distinct from one another in structure and function. They are distinct in structure because they have separate nucleic acid sequences, that is they are fragments and portions of different genes and have nucleic acid sequences which are distinct form one another. They can be used in the detection of different genes. Likewise, the methods

of groups III and IV are separate and distinct from one another because they are directed at the detection of different target sequences, namely the VT1 or the VT2 genes.

4. Inventions I and III and inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of inventions I and II can be used in materially different processes, for example in hybridization assays or PCR assays for the detection of the genes from which they originate.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-IV require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

8. For group I, SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5.

9. For group II, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, and SEQ ID NO: 14.

10. For group III, there are two sets of species:

a. a first oligonucleotide: SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5 and also

b. a second oligonucleotide: SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, and SEQ ID NO: 18;

11. For group IV, there are two sets of species:

c. a first oligonucleotide: SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, and SEQ ID NO: 14 and also

d. a second oligonucleotide: SEQ ID NO: 19, SEQ ID NO: 20, SEQ ID NO: 21, SEQ ID NO: 22, and SEQ ID NO: 23.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. During a telephone conversation with Vincent Shier on 9/5/03 a provisional election was made with traverse to prosecute the invention of Group III, claims 3, 5, 6, and 7, further electing first oligonucleotide SEQ ID NO: 2 and second oligonucleotide SEQ ID NO: 15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1, 2, 4, and 8 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

14. Claim 3 is objected to because it contains a plurality of method steps but not indentations to separate the steps. MPEP 608.01(m) states "Where a claim sets forth a plurality of elements

or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i)." The claims would be much easier to read and follow if indentations were used to separate steps.

15. Claim 5 is objected to over the recitation "and changes ... is measured" in lines 6-7 of the claim as there is not proper subject verb agreement between the plural "changes" and the singular "is."

Claim Rejections - 35 USC § 112

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 3, 5, 6, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite over the recitation "said double-stranded DNA produces an RNA transcription product" because it is not clear if this is an active process step, or what the process step would actually be. The double-stranded DNA is not capable itself of producing an RNA, but instead some sort of reaction must take place in order to form the RNA. For example, and a transcription reaction. The claim recites that the double-stranded DNA produces the RNA transcription product in the presence of an RNA polymerase (i.e. that this is a property of the double stranded DNA) but the claim never actually directs that the polymerase is present and that the transcription occurs. The claim should be clarified to make this inclusion. Claims 5, 6, and 7 depend from claim 3 and do not remedy this deficiency.

Claim 3 is further indefinite because the phrase "the amplification process" in line fifteen of the claim does not have proper antecedent basis in the claim. The claim does not previously refer to an amplification process, only processes of detecting, synthesis of a cDNA, digestion, and production of a single stranded DNA. There is not mention of an amplification process in the claims, and thus, it is not clear from the claim what processes is being referred to as an "amplification" process. Claims 5, 6, and 7 depend from claim 3 and do not remedy this deficiency.

Claim 3 is further indefinite because the recitation "said RNA polymerase promoter sequence" in the last full line of the claim lacks proper antecedent basis in the claim. The claim previously recites a "promoter sequence capable of transcribing RNA...employing a DNA-dependent DNA polymerase" but does not recite that this sequence is an RNA polymerase promoter, especially since it is to promote transcription using a DNA polymerase. It is not clear what promoter "said RNA polymerase" promoter is referring to. Claims 5, 6, and 7 depend from claim 3 and do not remedy this deficiency.

Claim 7 is indefinite because the recitation "said VT1 mRNA" in line 3 of the claim lacks proper antecedent basis in the claim because the claim does not previously recite a VT1 mRNA, only a VT1 RNA. It is not clear if applicant intends to refer to the previously mentioned RNA or if applicant intends to refer only to a mRNA.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bekkaoui *et al.* (US 6136533) in view of all of the following references: Gilgen *et al.* (Research in Microbiology (1998 Feb) 149(2) 145-154), Calderwood *et al.* (PNAS USA, Vol. 84, p. 4364-4368), and Buck *et al.* (Biotechniques (1999) 27(3):528-536).

The instant method is drawn to a process for detecting verotoxin 1 RNA (VT1 RNA). The basic methodology used in the method provided by Bekkaoui *et al.* Bekkaoui *et al.* teach a process of detecting nucleic acid in a sample, wherein a specific sequence :

forming a cDNA with a RNA-dependent DNA polymerase using a specific sequence of a RNA present in a sample as a template, thereby producing a RNA-DNA double strand (Col. 13, lines 25-34);

digesting the RNA of said RNA-DNA double strand with Ribonuclease H to form a single stranded DNA (Col. 13, lines 34-36);

using the single stranded DNA as a template for production of a double stranded DNA having a promoter sequence capable of transcribing said RNA sequence or a RNA comprising a

sequence complementary to said RNA sequence with a DNA-dependent DNA polymerase, said double-stranded DNA produces a RNA transcription product in the presence of RNA polymerase, and said RNA transcription product is subsequently used as the template for the single stranded DNA production with said RNA-dependent DNA polymerase (Col. 13, lines 36-40).

The method taught by Bekkaoui *et al.* employs a first primer having a sequence homologous to said specific sequence and a second primer having a sequence complementary to said specific sequence, wherein either the second primer has a sequence having an RNA polymerase promoter added at its 5'-region (Col. 13, lines 15-17).

Bekkaoui *et al.* suggest that suitable target nucleic to be used with their disclosed methodologies include nucleic acid molecules obtained from "viruses, prokaryotes, or eukaryotes (Col. 5, lines 66-67)." Bekkaoui *et al.* further teach their methods have advantages over other nucleic acid technologies, for example PCR, because they are simple, rapid and inexpensive to use, and unlike other amplification technologies (like PCR) can be accomplished at a relatively constant temperature (Col. 2, lines 15-20)." Bekkaoui *et al.* do not teach a method for detecting VT1 RNA in particular, and further do not teach a method wherein a primer comprising 10 or more nucleotide from instant SEQ ID NO: 2 or SEQ ID NO: 15 is used.

Gilgen *et al.* exemplify an amplification reaction in which the VT1 gene is utilized as a target (p. 148). Gilgen *et al.* use primers based on the sequence of Calderwood *et al.*

Calderwood *et al.* teach the sequence of the full length VT1 gene from E. coli (Figure 2; referred to by Calderwood *et al.* as SltA). Instant SEQ ID NO: 2 and instant SEQ ID NO: 15 are within the sequence taught by Calderwood *et al.* Instant SEQ ID NO: 2 consists of the

complement of nucleotides 776-795 of the sequence taught by Calderwood *et al.* and instant SEQ ID NO: 15 consists of nucleotides 660-684 of the sequence taught by Calderwood *et al.*

Buck *et al.* compare a wide variety of primers from within a single target sequence and demonstrate that primers selected using a variety of methods all function as equivalents. Buck expressly provides evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18 mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when the experiment was repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95 control primers functioned, which represent 1/3 of all possible primers in the target region. This clearly shows that every primer would have a reasonable expectation of success.

Therefore, given the general method taught by Bekkaoui *et al.*, the fact that Gilgen *et al.* exemplify that the VT1 gene as a target for amplification and detection, and the sequence of the VT1 gene taught by Calderwood *et al.*, it would have been prima facie obvious to one of

ordinary skill in the art at the time the invention was made to have used the modified the taught by Bekkaoui *et al.* so as to have used them for the detection of the VT1 gene. One would have been motivated to use the methods taught by Bekkaoui *et al.* in order to take advantage of the methodology as taught by Bekkaoui *et al.*, who state that the method can be carried out "in the presence of heterologous nucleic acid molecules, at a relatively constant temperature and without serial addition of reagents (Col. 13, lines 1-13)." One would have been motivated to detect the VT1 gene because it was a known target useful for the detection of toxigenic E. coli in a sample. With regard to the selection of primers, one would have been motivated to select any primers from within the VT1 gene as taught by Calderwood *et al.* for the detection of the gene in the methods taught by Bekkaoui *et al.*, as each of these primers would be expected to function as functional equivalents of one another for the detection of the VT1 gene, including primers which comprise at least 10 contiguous nucleotides of SEQ ID NO: 2 and SEQ ID NO: 15. In the absence of a secondary consideration, such as unexpected results, the invention is *prima facie* obvious.

21. Claims 5, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bekkaoui *et al.* (US 6136533) in view of all of the following references: Gilgen *et al.* (Research in Microbiology (1998 Feb) 149(2) 145-154), Calderwood *et al.* (PNAS USA, Vol. 84, p. 4364-4368), and Buck *et al.* (Buck et al (Biotechniques (1999) 27(3):528-536) as applied to 3 above, and further in view of Ishiguro *et al.* (Nucleic Acids Research, 1996, Vol. 24, No. 24, pages 4992-4997).

The teachings of Bekkaoui *et al.* in view of Gilgen *et al.*, Calderwood *et al.* and Buck *et al.* are applied to claims 5, 6, and 7 as they are applied in the previous rejection.

With regard to claim 5, these together do not provide a method wherein said amplification is carried out in the presence of an oligonucleotide probe labeled with an intercalator fluorescent dye wherein the probe is complementary to the RNA transcription product and wherein the binding of the probe to said RNA transcription product results in a change of the fluorescent property relative to that of a situation where a complex formation is absent, then measuring the fluorescence intensity of the reaction solution. With regard to claim 6, therefore, these do no teach that the probe is complementary to at least a portion of the sequence of the RNA transcription product, nor do these combined specifically teach the sequence of the probe as being at least 10 contiguous bases of SEQ ID NO: 24 (as recited in claim 7).

Ishiguro *et al.* teach methods wherein a probe labeled with an intercalator fluorescent dye is included in an *in vitro* transcription application in order to provide an easy and specific homogeneous method to detect a nucleic acid sequence (p. 4992). With regard to claim 6, the probe used by Ishiguro *et al.* is designed to be complementary to a portion of the RNA transcription product, and the fluorescent property changes when the probe is bound (p. 4992 and 4994, first column). Ishiguro *et al.* teach that "The present success of the applicability of the probe to real-time monitoring of the in vitro transcription showed that YO-linked DNA probe can be a powerful tool with which to construct a new methodology to study the dynamics of gene expression, and also to provide a more practical way of detecting and quantifying a target sequence in a clinical specimen specifically in a homogeneous format (p. 4997)." Thus, in light

of the teachings of Ishiguro *et al.*, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have included an oligonucleotide probe labeled with an intercalator fluorescent dye wherein the probe is complementary to the RNA transcription product in the method taught by Bekkaoui *et al.* in view of Gilgen *et al.*, Calderwood *et al.* and Buck *et al.* The ordinary practitioner would have been motivated to include such a probe in order to provide a practical way of detecting and quantifying target sequence in a clinical specimen in a homogeneous format, as is taught by Ishiguro *et al.*

With regard to claim 7, instant SEQ ID NO: 24 consists of the complement of nucleotides 730-751 of the sequence taught by Calderwood *et al.* Given the combined teachings of Bekkaoui *et al.* in view of Gilgen *et al.*, Calderwood *et al.*, and Buck *et al.* and further in view of Ishiguro *et al.*, it would have further been prima facie obvious to one of ordinary skill in the art to have selected a probe from within the sequence taught by Calderwood *et al.* to have used for detection of the isothermal amplification product. One would have been motivated to select any probe within the selected primers, as all probes, like the primers, would be expected to function as equivalents.

Conclusion

22. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C Switzer
Examiner
Art Unit 1634

October 24, 2003